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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,881	12/07/2005	Koetsu Saito	10873.1804USWO	2841
53148 7590 09/25/2007 HAMRE, SCHUMANN, MUELLER & LARSON P.C. P.O. BOX 2902-0902 MINNEAPOLIS, MN 55402			EXAMINER BOR, HELENE CATHERINE	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 09/25/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/559,881	Applicant(s) SAITO, KOETSU	
	Examiner Helene Bor	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/07/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Ultrasonic Probe with an Acoustic Medium.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claim 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakimuddia'156 (US Patent No. 6,612,156 B1) and further in view of Nunomura'355 et al. (US Patent No. 7,001,355 B2).

Claim 1: Hakimuddia'156 teaches an ultrasonic probe (Figure 1, Element 20) comprising: an ultrasonic transducing part for transmitting and receiving an ultrasonic wave (Col. 4, Line 18-20); an outer case for storing the ultrasonic transducing part (Col.

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4, Line 18-20) and an acoustic medium [sample] charged in the outer case (Col. 3, Line 46-51). However, Hakimuddia'156 teaches the Poly(Butylene) Glycol and polybutylene glycol not specifically 1,2-butylene glycol or 1,3-butylene glycol. However, Nunomura'355 teaches wherein the acoustic medium contains butylene glycol (Col. 11, Line 13-40) and specifically 1,3-butylene glycol. It would have been obvious to one of ordinary skill in the art to combine the teachings of Hakimuddia'156 and Nunomura'355 in order to use a composition can effectively deliver the ultrasound to the skin without leaving the skin feeling sticky (Col. 2, Line 10-18). Nunomura'355 does not specifically mention 1,3-butylene glycol. However according the Miller (Miller, L.M. "Investigation of selected potential environmental contaminants: ethylene glycols, propylene glycols and butylenes glycols: Final Report". Franklin Research Center, Philadelphia, PA. 01 May 1979. PB-80-109119), butylene glycol has four isomers, 1,3-, 1,4- 2,3- and 1,2-butylene glycol. It would have been obvious for one of ordinary skill in the art to try one of the four butylenes glycol known isomers and trying one isomer over the other isomer lacks an inventive step.

Claim 2/1: Hakimuddia'156 teaches the ultrasonic probe (Figure 1, Element 20) but fails to specifically teach 1,3-butylene glycol. However, Nunomura'355 teaches wherein the acoustic medium is formed of only butylene glycol (Col. 11, Line 13-40). It would have been obvious to one of ordinary skill in the art to combine the teachings of Hakimuddia'156 and Nunomura'355 in order to use a composition can effectively deliver the ultrasound to the skin without leaving the skin feeling sticky (Col. 2, Line 10-18).

Claim 3/1: Hakimuddia'156 teaches the ultrasonic probe (Figure 1, Element 20) and

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the temperature range (Col. 6, Line 65-67) but fails to specifically teach butylene glycol. However, Nunomura'355 teaches wherein the acoustic medium further contains at least one material that is soluble in butylene glycol and a liquid (Col. 11, Line 13-40). It would have been obvious to one of ordinary skill in the art to combine the teachings of Hakimuddia'156 and Nunomura'355 in order to use a composition can effectively deliver the ultrasound to the skin without leaving the skin feeling sticky (Col. 2, Line 10-18).

Claim 4/3/1: Hakimuddia'156 teaches the ultrasonic probe (Figure 1, Element 20) but fails to specifically teach 1,3-butylene glycol. However, Nunomura'355 teaches wherein the material is at least one selected from the group consisting of ethylene glycol, 1,3-butylene glycol, and water (Col. 11, Line 13-40). It would have been obvious to one of ordinary skill in the art to combine the teachings of Hakimuddia'156 and Nunomura'355 in order to use a composition can effectively deliver the ultrasound to the skin without leaving the skin feeling sticky (Col. 2, Line 10-18).

Claim 5/4/3/1: Hakimuddia'156 teaches the ultrasonic probe (Figure 1, Element 20) but fails to specifically teach 1,3-butylene glycol. However, Nunomura'355 teaches wherein the material is 1,3-butylene glycol (Col. 11, Line 30-40). It would have been obvious to one of ordinary skill in the art to combine the teachings of Hakimuddia'156 and Nunomura'355 in order to use a composition can effectively deliver the ultrasound to the skin without leaving the skin feeling sticky (Col. 2, Line 10-18).

Claim 6/1: Hakimuddia'156 teaches the ultrasonic probe (Figure 1, Element 20) but fails to teach specific wt % of butylene glycol. However, Nunomura'355 teaches wherein the acoustic medium contains 25 to 100 wt % of butylene glycol (Col. 11, Line

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13-15 & 30-40). It would have been obvious to one of ordinary skill in the art to combine the teachings of Hakimuddia'156 and Nunomura'355 in order to use a composition can effectively deliver the ultrasound to the skin without leaving the skin feeling sticky (Col. 2, Line 10-18).

Claim 7/1: Hakimuddia'156 teaches the ultrasonic probe, wherein the acoustic medium has an acoustic impedance of 1.45 to 1.517 MRayl at a temperature of 20.degree. C., and produces an ultrasonic attenuation of 0.07 to 0.091 dB/mm at a frequency of 3 MHz (Col. 3, Line 66 – Col. 4, Line 4 & Col. 6, Line 12-26).

Claim 8/1: Hakimuddia'156 teaches the ultrasonic probe, comprising a mechanism for oscillating or rotating the ultrasonic transducing part (Col. 4, Line 33-35).

Claim 9/1: Hakimuddia'156 teaches the ultrasonic probe, wherein the ultrasonic transducing part includes an array element in which a plurality of transducers are arranged (Figure 1, Element 20 & Col. 5, Line 32-36).

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. ATALA, ANTHONY et al. ULTRASOUND-MEDIATED DRUG DELIVERY, 05/09/2002. US 20020055702 A1.

b. Eppstein; Jonathan A. Enhancement of transdermal monitoring applications with ultrasound and chemical enhancers, 03/03/1998. US 5722397 A.

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c. MCDANIEL, DAVID H. ULTRASOUND ENHANCEMENT OF
PERCUTANEOUS DRUG ABSORPTION, 11/15/2001. US 20010041856 A1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hcb


ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER